DETAILED ACTION

Current Status of 10/509772

1. The restriction dated 4/25/2007 was made FINAL in the office action dated 6/29/2007.

2. The rejection under 35 USC 112 1st paragraph regarding claims 1-2 and 19-22 is overcome by the amendment filed 10/01/2007.

3. As a result of the restriction and the non-final action mailed 6/29/2007, only claims 11-12 are being examined in the current office action.

Rejections Maintained

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 11-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Rowley et al. (*Journal of Medicinal Chemistry*, **2001**, *44 (4)*, 477-501, ref CA of 9/28/2004 IDS) and Aghajanian et al. (*Neuropsychopharmacology*, **1999**, *21 (56)*, S122-S133, ref CB of 9/28/2004 IDS).

Rowley et al. teach the use of olanzapine (page 479, column 1, compound 10) as an atypical antipsychotic drug for treating schizophrenia. Rowley teaches that olanzapine is part of a class of antipsychotics in which the 5-HT_2/D_2 ratio is more important than the absolute affinity for each receptor individually. An antipsychotic drug can be considered "atypical" if extrapyramidal side effects (EPS) are reduced and/or they have an enhanced spectrum of antipsychotic efficacy (Aghajanian et al., page S122, paragraph 2-S123, paragraph 1, lines 1-2). Rowley et al. do not teach the combination of olanzapine with other active ingredients.

Aghajanian et al. teach the use of group II/III metabotropic glutamate agonists that suppress the 5-HT-induced release of glutamate. Said agonists are therapeutic targets for the treatment of schizophrenia. Aghajanian et al. specifically discuss LY 354740. They do not teach combination of LY 354740 with other active ingredients.

In re Kerkhoven (205 USPQ 1069) supports this 103 rejection of the combination of the two active agents. *In re Kerkhoven* deals with the production of particulate detergent compositions containing a mixture of anionic and nonionic active detergent materials. The ruling in the case concerning patentability states "it is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for the same purpose in order to form third composition that is to be used for very same purpose." In the case of the instant claims, each compound is a known antipsychotic agent, and it is a case of prima facie obvious to combine the components together to form a composition for an identical purpose. Thus, it is obvious to combine two antipsychotic compounds together. The method for using the combination of active agents to perform together, the function each is noted for separately in the prior art, is also seen to be prima facie obvious.

The examiner has noted the comparative data in the specification (figures 5 and 6). Figures 5 and 6 are noted for the synergy shown between olanzapine and the different isomers

of the elected compound. In figure 5, the ambulations of phencyclidine (PCP) fed rats are decreased by ~2000 using the combination of olanzapine and the elected compound, compared to the number of ambulations under olanzapine alone (3000). In figure 6, the number of ambulations for olanzapine (600) was decreased to 400 ambulations when the rats were treated with the combination of olanzapine and the elected compound. Thus, the synergy between olanzapine and the isomers of the elected compound is observed. However, claims 11-12 directed to the components tested are not limited to the treatment of schizophrenia nor are the claims limited to "synergistic" amounts.

Allowable Subject Matter

7. No claims are allowed.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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